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EXAMINER	
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1753	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/020,776	Applicant(s) FRITSCH ET AL.	
	Examiner ALEX NOGUEROLA	Art Unit 1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23 and 46-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *29-43* is/are allowed.

6)☒ Claim(s) *1-15,25-28 and 46-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicants' amendment of February 14, 2005 does not render the application allowable. The allowability of claim 1 is withdrawn because (1) upon reconsideration the examiner believes he has read the phrase "analyte-selective organic materials" too narrowly. Barring a contrary showing, such materials do not require a chemical or biochemical reactive element, but could be broadly construed to include an organic membrane that is selectively permeable to analyte, and (2) even if the phrase "analyte-selective organic materials" is narrowly construed to require a chemical or biochemical reactive element, having such a material suspended over cavity comprising microelectrodes was known at the time of the invention as discussed below in the new rejection of claim 1 , which uses newly cited JP 03176657 A.

Status of Rejections Pending Since the Office action of August 09, 2004

2. All previous rejections are withdrawn.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over the English language translation of Urban (WO/12314 A1) ("Urban") in view of Hill et al. (US 5,820,551) ("Hill"), D'Orazio et al. (US 5,773,270) ("D'Orazio"), Wehmeyer et al. ('Electroanalytical Properties of Band Electrodes of Submicrometer Width," Anal. Chem. 1985, 57, 1913-1916) ('Wehmeyer"), and Thormann et al. ("Voltammetre at Linear Gold and Platinum Microelectrode Arrays Produced by Lithographic techniques," Anal. Chem. 1985, 57, 2764-2770) ("Thormann")

Urban discloses an electrochemical sensing device wherein analyte-selective organic materials are suspended over a cavity penetrating alternating microelectrode layers and insulating layers. See the first paragraph on page 3, Figure 13, the second full paragraph on page 11; and the top paragraph on page 20, which bridged over form page 19.

Urban does not mention (1) whether the analyte-selective membranes are organic, and (2) *sub*microelectrode layers.

As for organic analyte-selective membranes, a large variety of organic membranes were known at the time of the invention suitable for use to cover the sensing region of an electrochemical device. See for example the D'Orazio abstract, Figures 1-3 and col. 4:7 – col. 8:15, which discloses various prior art references with different organic membranes; and col. 6:65 – col. 7:13 in Hill. It was within the skill of one with ordinary skill in the art to select a suitable membrane from known membranes. The selection would be based mainly on permeability of the membane to the analyte, impermeability to substances considered interferants, and compatability or

biocompatability of the membrane with the sample environment. Also, as shown by D'Orazio more than one membrane may be used together.

As for submicroelectrodes, although Urban only mentions microelectrodes barring a showing to the contrary providing submicroelectrodes instead is just a change in size that was within the skill of one with ordinary skill in the art at the time of the invention. See the abstracts of Thormann and Wehnmaeyer.

7. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over the English language translation of Urban (WO/12314 A1) ("Urban") in view of Hill et al. (US 5,820,551) ("Hill"), D'Orazio et al. (US 5,773,270) ("D'Orazio"), and Figures 4(d) and 3 of and the Derwent abstract for JP 03-176657 A ("JP 03-176657 A"). Note for this rejection "analyte-selective organic materials" is assumed to require a chemical or biological reactive agent.

Urban discloses an electrochemical sensing device wherein a cavity penetrates alternating microelectrode layers and insulating layers. See the first paragraph on page 3, Figure 13, and the second full paragraph on page 11.

Urban does not mention (1) suspending analyte-selective organic materials over the cavity, and (2) *sub*microelectrode layers.

As for suspending analyte-selective organic materials over the cavity, Urban does disclose providing analyte selective materials (see page 7, first full paragraph),

although not suspended over the cavity. However, as shown by JP 03-176657 A suspending analyte-selective organic materials over a cavity comprising more than one electrode was known at the time of the invention ("... an enzyme is fixed on the gas permeable membrane"). In light of JP 03-176657 A whether the analyte-selective materials are placed within the cavity or suspended above the cavity is arbitrary. *Alternatively*, at least one benefit may accrue if the embodiment of Figure 10 of Urban is used. In this case one electrode is outside the cavity, so by placing the analyte-selective materials over the cavity this will ensure that all of the electrodes are exposed to the same electrolyte solution composition, which may improve accuracy.

As for submicroelectrodes, although Urban only mentions microelectrodes barring a showing to the contrary providing submicroelectrodes instead is just a change in size that was within the skill of one with ordinary skill in the art at the time of the invention. See the abstracts of Thormann and Wehnmaeyer.

8. Claims 2-11, 13, 14, 16-24, 26, 46, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over the English language translation of Urban et al. (WO 90/12314 A1), hereafter "Urban," in view of Ufer (US 2003/0085124 A1), hereafter "Ufer," and Douglas et al. (US 2003/0106810 A1), hereafter "Douglas," Pace (US 4,225,410), hereafter ("Pace"), and Diebold et al. (US 5,437,999) ("Diebold"). It should be noted that although Ufer and Douglas do not have priority before Applicants' earliest

priority date of April 30, 1998, the examiner has not found support for a flexible polymer substrate in a microcavity device as claimed in any of Applicants' priority documents. Thus, until demonstrated otherwise, claims 2-25 will be accorded a priority date of December 12, 2001, which is the filing date of the instant application.

Addressing claim 2, Urban teaches a microcavity device comprising

(a) a substrate (element **5** in Figures 10-15);

(b) integrated, independently addressable electrodes (elements **1**, **2**, and **3** in Figures 10-15);

(c) conducting layers connected to the electrodes (not labeled but shown in or suggested by Figures 10-15), the conducting layers being planar and parallel to one another (inferred from Figures 9-15, which together show conducting layers extending from electrodes that are planar and parallel);

(d) an insulating layer separating adjacent conducting layers (element **4** in Figures 10-13);

(e) the conducting layers and the insulating layer being on top of the substrate (Figures 10-13); and

(f) at least one microcavity penetrating the conducing layers and the insulating layer, the microcavity having a depth, a diameter, and a top opening (Figures 10-13; the last full paragraph on page 15, claim 15, and the first full paragraph on page 18).

Urban does not mention using a flexible polymer substrate. Urban is in fact silent on possible substrate materials. However, Urban does disclose using polyimide insulator layers (last paragraph on page 17). Douglas and Ufer both teach microscale electrochemical sensor devices made of thin layers of insulating and conducting materials on a flexible substrate (the abstract; Figure 5; and paragraphs [0024] and [0026] in Douglas and the abstract; Figure 4; and paragraph [0027] and [0029] in Ufer). It would have been obvious to one with ordinary skill in the art at the time the invention was made to use a flexible substrate as taught by Douglas or Ufer in the invention of Urban because they each teach that a plurality of sensing device can then be made using continuous processing techniques (paragraph [0013] in Ufer and paragraph [0013] in Douglas), which, as taught by Douglas, "results in high volume manufacturing capability an [sic] substantial cost reductions over step and repeat processes." Also, Douglas and Ufer disclose polyimide as a possible flexible substrate material (paragraph 0021] in Douglas and paragraph [0022] in Ufer), which, as mentioned above, Urban discloses may be used for the insulating layers.

In the alternative, Ufer and Douglas are not needed to provide motivation for a flexible substrate because Urban already teaches insulating layers made from a flexible material (polyimide) and Urban teaches having the microcavity built into a catheter, which may be used for taking measurements in body cavities (page 12, first full paragraph and page 20, first full paragraph). In a catheter embodiment it would have been obvious to one with ordinary skill in the art at the time the invention was made to have the substrate be flexible so that the catheter can be maneuvered in the patient's body with minimum discomfort and injury to the patient.

More generally, if the sensor is to be inserted into a person it would have been obvious to one with ordinary skill in the art at the time of the invention to make the sensor flexible for the same reasons as for making a catheter embodiment flexible.

Urban also does not mention contact pads for the conducting layers. Pace discloses an integrated array of electrochemical sensors each sensor having a cavity and planar, parallel electrodes with conducting layers and contact pads. See the abstract and Figures 3, 4, and 6. Diebold discloses an electrochemical sensor having spaced planar, parallel electrodes with conducting layers and contact pads. See the abstract and Figures 5 and 6. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide contact pads as taught by Urban and Diebold in the invention of Urban as modified by Ufer and Douglas because it would then be more convenient to make measurements. Sample need only applied to the small easily held sensor rather than a large bulky meter with power source and display. Also, since the sample is only applied to the sensor contamination of the meter is avoided as only the contact pads contact the meter. Furthermore, the meter can be used for sensors that are configured for different analyses. One sensor may measure glucose and fructose and another sensor may measure cholesterol and lactose, for example.

Addressing claims 3 and 17, Urban discloses having a membrane over the electrodes (second paragraph on page 11 and claim 12). From Figures 10-13 one with ordinary skill in the art at the time of the invention would have envisaged the membrane as covering the top opening.

Indeed, for the embodiments in Figures 10 and 12 the membrane must cover the top opening if it is also to cover all of the electrodes.

Addressing claims 4, 5, and 18, the membrane is for "selective acquisition of certain electroactive species" (page 11, second paragraph of Urban). That is, the membrane is selectively permeable. One with ordinary skill in the art at the time of the invention would have understood that the membrane is to be permeable to analytes of interest and necessary or useful electrolytes.

Addressing claims 6, 7, 10, 19, 20, and 23 although no specific dimensions are mentioned by Urban, barring evidence to the contrary, such as unexpected results, the dimensions claimed by Applicants are just a matter of scaling the device of Urban as modified by Ufer and Douglas to best accommodate the expected sample volume because Urban clearly teaches micro and submicron scale dimensions and measuring very small analyte concentrations (second paragraph on page 3; page 5, sixth line form the bottom to last line on page 6; claims 1 and 15; and next to last paragraphs on pages 7 and 15).

Addressing claims 8 and 21, Urban discloses band and disc electrodes (electrode **1** is a disc electrode, and electrodes **2** and **3** are band electrodes. See Figures 13 and 14, for example).

Addressing claims 9 and 22, Urban discloses at least two electrodes in the cavity (Figures 10-15).

Addressing claims 11, 13, and 24, Urban discloses providing a plurality of microcavities (Figures 14 and 15), each microcavity being a complete electrochemical cell (each microcavity comprises a measurement electrode (2), a counterelectrode (3), and a reference
electrode (1)).

Addressing claims 14 and 26, that the device is a recessed disk microelectrode may be seen form Figures 10-13.

Addressing claim 16, Urban teaches a microcavity device comprising

(a) a substrate (element **5** in Figures 10-15);

(b) integrated, independently addressable electrodes (elements **1**, **2**, and **3** in Figures 10-15);

(c) conducting layers connected to the electrodes (not labeled but shown in or suggested by Figures 10-15), the conducting layers being planar and parallel to one another (inferred from Figures 9-15, which together show conducting layers extending from electrodes that are planar and parallel);

(d) an insulating layer separating adjacent conducting layers (element **4** in Figures 10-13);

(e) the conducting layers and the insulating layer being on top of the substrate (Figures 10-13); and

(f) at least one microcavity penetrating the conducing layers and the insulating layer, the microcavity having a depth, a diameter, and a top opening (Figures 10-13; the last full paragraph on page 15, claim 15, and the first full paragraph on page 18);

(g) wherein the microcavity is a self-contained electrochemical cell (each microcavity comprises a measurement electrode (2), a counterelectrode (3), and a reference

electrode (1). See second full paragraph on page 14); and

(h) a device for measuring electrical potential difference or current between electrodes (Urban discloses at least making potentiodynamic measurements (last line on page 6 bridging to page 7).

Urban does not mention using a flexible polymer substrate. Urban is in fact silent on possible substrate materials. However, Urban does disclose using polyimide insulator layers (last paragraph on page 17). Douglas and Ufer both teach microscale electrochemical sensor devices made of thin layers of insulating and conducting materials on a flexible substrate (the abstract; Figure 5; and paragraphs [0024] and [0026] in Douglas and the abstract; Figure 4; and paragraph [0027] and [0029] in Ufer). It would have been obvious to one with ordinary skill in the art at the time the invention was made to use a flexible substrate as taught by Douglas or Ufer in the invention of Urban because they each teach that a plurality of sensing device can then be made using continuous processing techniques (paragraph [0013] in Ufer and paragraph

[0013] in Douglas), which as taught by Douglas "results in high volume manufacturing capability an [sic] substantial cost reductions over step and repeat processes." Also, Douglas and Ufer disclose polyimide as a possible flexible substrate material (paragraph 0021] in Douglas and paragraph [0022] in Ufer), which, as mentioned above, Urban discloses may be used for the insulating layers.

In the alternative, Ufer and Douglas are not needed to provide motivation for a flexible substrate because Urban already teaches insulating layers made from a flexible material (polyimide) and Urban teaches having the microcavity built into a catheter, which may be used for taking measurements in body cavities (page 12, first full paragraph and page 20, first full paragraph). In a catheter embodiment it would have been obvious to one with ordinary skill in the art at the time the invention was made to have the substrate be flexible so that the catheter can be maneuvered in the patient's body with minimum discomfort and injury to the patient.

Urban also does not mention contact pads for the conducting layers. Pace discloses an integrated array of electrochemical sensors each sensor having a cavity and planar, parallel electrodes with conducting layers and contact pads. See the abstract and Figures 3, 4, and 6. Diebold discloses an electrochemical sensor having spaced planar, parallel electrodes with conducting layers and contact pads. See the abstract and Figures 5 and 6. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide contact pads as taught by Urban and Diebold in the invention of Urban as modified by Ufer and Douglas because it would then be more convenient to make measurements. Sample need only applied to the small easily held sensor rather than a large bulky meter with power source and display. Also, since the sample is only applied to the sensor contamination of the meter is avoided as only the

contact pads contact the meter. Furthermore, the meter can be used for sensors that are configured for different analyses. One sensor may measure glucose and fructose and another sensor may measure cholesterol and lactose, for example.

Addressing claims 46 and 48, Urban as modified by Ufer, Douglas, Pace, and Diebold does not mention providing an adhesion layer between the insulating and conducting layers and the conducting layer and the substrate. Diebold discloses providing an adhesion layer between a conducting layer and a non-conducting layer. See col. 3:50-65. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide an adhesion layer as taught by Diebold in the invention of Urban as modified by Ufer, Douglas, Pace, and Diebold because as taught by Diebold, the adhesion layer will increase adhesion between the conducting material and the support material, as well as stabilize the microstructure of conducing material. See col. 3:62-65.

9. Claims 12 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Urban in view of Ufer, Douglas, Pace, and Diebold as applied to claims 2-11 13, 14, 16-24, 26, 46, 48 above, and further in view of Wolf et al. (US 6,376,233 B1), hereafter "Wolf."

Urban does not mention including at least 96 wells in the microcavity device, although as noted in the rejection of claim 11 Urban does disclose a plurality of wells. Wolf discloses a microtiter plate having 96 wells with a sensor, which may be an electrode-based sensor, in each well (abstract; Figures 3 and 4; col. 2, ll. 46-53; and claim 12). Barring evidence to the contrary, such as unexpected results, to provide 96 wells as taught by Wolf in the invention of Urban as modified by Ufer and Douglas (or just Urban if the alternative motivation of claims 2 and 16 is used) is just further multiplication of parts for a multiplied effect, which is in itself obvious. It would have been obvious to one with ordinary skill in the art at the time the invention was made to proved at least 96 sensor wells as taught by Wolf in the invention of Urban as modified by Ufer and Douglas (or just Urban if the alternative motivation of claims 2 and 16 is used) so that many samples can be simultaneously and independently analyzed.

10. Claims 15, 27, 47, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over the English language translation of Urban et al. (WO 90/12314 A1), hereafter "Urban," in view of Pace (US 4,225,410), hereafter ("Pace"), and Diebold et al. (US 5,437,999) ("Diebold").

Addressing claim 15, Urban teaches a microcavity device comprising

(a) a silicon substrate (element **5** in Figures 10-15; Urban discloses silicon insulating layers (first full paragraph on page 18);

(b) integrated, independently addressable electrodes (elements **1**, **2**, and **3** in Figures 10-15);

(c) conducting layers connected to the electrodes (not labeled but shown in or suggested by Figures 10-15), the conducting layers being planar and parallel to one another (inferred from Figures 9-15, which together show conducting layers extending from electrodes that are planar and parallel);

(d) an insulating layer separating adjacent conducting layers (element **4** in Figures 10-13);

(e) the conducting layers and the insulating layer being on top of the substrate (Figures 10-13); and

(f) at least one microcavity penetrating the conducing layers and the insulating layer, the microcavity having a depth, a diameter, and a top opening (Figures 10-13; the last full paragraph on page 15, claim 15, and the first full paragraph on page 18).

As noted above, Urban discloses silicon insulating layers (first full paragraph on page 18). It would have been obvious to one with ordinary skill in the art at the time the invention was made to also have the substrate made of silicon because this would simplify the manufacturing process as the substrate is essentially just another insulating layer, except, perhaps, thicker.

Urban also does not mention contact pads for the conducting layers. Pace discloses an integrated array of electrochemical sensors each sensor having a cavity and planar, parallel electrodes with conducting layers and contact pads. See the

abstract and Figures 3, 4, and 6. Diebold discloses an electrochemical sensor having spaced planar, parallel electrodes with conducting layers and contact pads. See the abstract and Figures 5 and 6. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide contact pads as taught by Urban and Diebold in the invention of Urban as modified by Ufer and Douglas because it would then be more convenient to make measurements. Sample need only applied to the small easily held sensor rather than a large bulky meter with power source and display. Also, since the sample is only applied to the sensor contamination of the meter is avoided as only the contact pads contact the meter. Furthermore, the meter can be used for sensors that are configured for different analyses. One sensor may measure glucose and fructose and another sensor may measure cholesterol and lactose, for example.

Addressing claim 27, Urban teaches a microcavity device comprising

(a) a silicon substrate (element **5** in Figures 10-15; Urban discloses silicon insulating layers (first full paragraph on page 18);

(b) integrated, independently addressable electrodes (elements **1**, **2**, and **3** in Figures 10-15);

(c) conducting layers connected to the electrodes (not labeled but shown in or suggested by Figures 10-15), the conducting layers being planar and parallel to

one another (inferred from Figures 9-15, which together show conducting layers extending from electrodes that are planar and parallel);

(d) an insulating layer separating adjacent conducting layers (element **4** in Figures 10-13);

(e) the conducting layers and the insulating layer being on top of the substrate (Figures 10-13); and

(f) at least one microcavity penetrating the conducing layers and the insulating layer, the microcavity having a depth, a diameter, and a top opening (Figures 10-13; the last full paragraph on page 15, claim 15, and the first full paragraph on page 18);

(g) wherein the microcavity is a self-contained electrochemical cell (each microcavity comprises a measurement electrode (2), a counterelectrode (3), and a reference

electrode (1). See second full paragraph on page 14); and

(h) a device for measuring electrical potential difference or current between electrodes (Urban discloses at least making potentiodynamic measurements (last line on page 6 bridging to page 7).

As noted above, Urban discloses silicon insulating layers (first full paragraph on page 18). It would have been obvious to one with ordinary skill in the art at the time the invention was made to also have the substrate made of silicon because this would simplify the manufacturing process as the substrate is essentially just another insulating layer, except, perhaps, thicker.

Urban also does not mention contact pads for the conducting layers. Pace discloses an integrated array of electrochemical sensors each sensor having a cavity and planar, parallel electrodes with conducting layers and contact pads. See the abstract and Figures 3, 4, and 6. Diebold discloses an electrochemical sensor having spaced planar, parallel electrodes with conducting layers and contact pads. See the abstract and Figures 5 and 6. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide contact pads as taught by Urban and Diebold in the invention of Urban as modified by Ufer and Douglas because it would then be more convenient to make measurements. Sample need only applied to the small easily held sensor rather than a large bulky meter with power source and display. Also, since the sample is only applied to the sensor contamination of the meter is avoided as only the contact pads contact the meter. Furthermore, the meter can be used for sensors that are configured for different analyses. One sensor may measure glucose and fructose and another sensor may measure cholesterol and lactose, for example.

Addressing claims 47 and 49, Urban as modified by Pace and Diebold does not mention providing an adhesion layer between the insulating and conducting layers and the conducting layer and the substrate. Diebold discloses providing an adhesion layer between a conducting layer and a non-conducting layer. See col. 3:50-65. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide an adhesion layer as taught by Diebold in the invention of Urban as modified by Ufer, Douglas, Pace, and Diebold because as taught by Diebold, the adhesion layer will increase adhesion between the conducting material and the support material, as well as stabilize the microstructure of conducing material. See col. 3:62-65.

11. Claims 28 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by the English language translation of Urban et al. (WO 90/12314 A1), hereafter "Urban."

Addressing claim 28, Urban teaches a microcavity device comprising

(a) a substrate (element **5** in Figures 10-15);

(b) integrated, independently addressable electrodes (elements **1**, **2**, and **3** in Figures 10-15);

(c) conducting layers connected to the electrodes (not labeled but shown in or suggested by Figures 10-15), the conducting layers being planar and parallel to one another (inferred from Figures 9-15, which together show conducting layers extending from electrodes that are planar and parallel);

(d) an insulating layer separating adjacent conducting layers (element **4** in

Figures 10-13);

(e) the conducting layers and the insulating layer[s] being on top of the substrate (Figures 10-13);

(f) at least one microcavity penetrating the conducing layers and the insulating layer[s], the microcavity having a depth, a bottom, a diameter, and a top opening (Figures 10-13; the last full paragraph on page 15, claim 15, and the first full paragraph on page 18); and

(g) wherein the disk electrode is recessed from the main plane of an insulting layer of the substrate such that it is flush with the bottom of the insulating layer (bottom of the microcavity?) See objection to the Drawings) (Figures 10-13).

Urban also does not mention contact pads for the conducting layers. Pace discloses an integrated array of electrochemical sensors each sensor having a cavity and planar, parallel electrodes with conducting layers and contact pads. See the abstract and Figures 3, 4, and 6. Diebold discloses an electrochemical sensor having spaced planar, parallel electrodes with conducting layers and contact pads. See the abstract and Figures 5 and 6. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide contact pads as taught by Urban and Diebold in the invention of Urban as modified by Ufer and Douglas because it would then be more convenient to make measurements. Sample need only applied to the small easily held sensor rather than a large bulky meter with power source and display. Also, since the sample is only applied to the sensor contamination of the meter is avoided as only the contact pads contact the meter. Furthermore, the meter can be

used for sensors that are configured for different analyses. One sensor may measure glucose and fructose and another sensor may measure cholesterol and lactose, for example.

The disk electrodes in Urban do not cover the entire bottom of the microcavity. However, barring a showing to the contrary this just a matter of desired dimensions for the overall dimensions of the sensor and its microcavites. For example, in the embodiment of Figure 11 of Urban if the microcavity is made the same width as that of the disk electrode (1) then the disk electrode will cover the entire bottom of the microcavity; however, the depth of the microcavity and thus the sensor thickness will have to be increased so that it can accommodate the same sample volume as t did before the microcavity width was narrowed.

Addressing claim 50, Urban as modified by Ufer, Douglas, Pace, and Diebold does not mention providing an adhesion layer between the insulating and conducting layers and the conducting layer and the substrate. Diebold discloses providing an adhesion layer between a conducting layer and a non-conducting layer. See col. 3:50-65. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide an adhesion layer as taught by Diebold in the invention of Urban as modified by Ufer, Douglas, Pace, and Diebold because as taught by Diebold, the adhesion layer will increase adhesion between the conducting material and

the support material, as well as stabilize the microstructure of conducing material. See col. 3:62-65.

Drawings

12. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the disk electrode flush with the bottom of the insulating layer (claim 28) must be shown or the feature canceled from the claim. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Allowable Subject Matter

13. Claims 29-43 are allowed.

14. The following is a statement of reasons for the indication of allowable subject matter:

a) Claim 29: the nonobvious limitation in the combination of limitations is the requirement that the microelectrode comprise "a silicon dioxide film grown on a silicon wafer by thermal oxidation" and the "wafer being spin-coated with polyimide."

Urban is silent on possible materials for the substrate other than indicating that it be inert (last paragraph on page 14, for example). Urban does disclose an embodiment having one or more silicon layers. However, in this embodiment the silicon layers are insulation layers (first full paragraph on page 18). There is no mention in Urban of using a silicon layer in combination with a polyimide layer as is required by Applicants' claim 29 ((a) and (g)-(i)). In fact, Urban *indirectly* discloses polyimide as an alternative to silicon for use in forming insulating layers because Urban discloses that if polyimide insulating layers are used then deep

microcavities may be formed (last paragraph on page 17 bridging to page 18). Urban also does not disclose a silicon oxide film on the silicon layers.

b) Claims 30 and 31 depends from allowable claim 29;

c) Claim 32: the nonobvious limitation in the combination of limitations is the requirement that the microelectrode comprise a silicon wafer to act as a substrate and polyimide insulating layers to separate the conducting.

Urban is silent on possible materials for the substrate other than indicating that it be inert (last paragraph on page 14, for example). Urban does disclose an embodiment having one or more silicon layers. However, in this embodiment the silicon layers are insulation layers (first full paragraph on page 18). There is no mention in Urban of using a silicon layer in combination with a polyimide layer as is required by Applicants' claim 29 ((a) and (g)-(i)). In fact, Urban indirectly discloses polyimide as an alternative to silicon for use in forming insulating layers because Urban discloses that if polyimide insulating layers are used then deep microcavities may be formed (last paragraph on
page 17 bridging to page 18); and

d) Claims 33-43 depend directly or indirectly from allowable claim 32.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alex Noguerola

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AU 1753
June 15, 2005